



SERVICE MANUAL LEVEL 1 Rev 01 – ADDENDUM 9

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

Changes to Chapter 1: Introduction; Section: Manual Outline and Conventions

Update 1: Clarification regarding the Service Manual and its Addendum

Q Core Medical cannot be responsible to any action performed by users that is not described in the Service Manual or its Addendum.

Changes to Chapter 1: Introduction; Section: Warnings and Safety Precautions, Proper Use of the Pump, Basic Infusion Safety Information

Update: New instruction for clamping the administration set

The first two paragraphs were replaced with the following:

To obtain maximum accuracy of the pump when used in a hospital or clinical environment, verify that the infusion container is positioned at a height of 50 cm above the pump. There is no restriction on the location of the infusion container in relation to the patient's heart.

Alarm conditions automatically stop the infusion and require immediate attention before the infusion can be restarted. When clamping the administration set, ensure the clamp is at least 20 cm (8 in) away from the pump, when possible. Note that if the dose rate is beyond the pump resolution of 0.1mL/h increments, the pump will increase or decrease the rate by up to 0.05mL/h. This flow rate (mL/h) is presented on the running screen during infusion.

Changes to Chapter 1: Introduction; Section: Warnings and Safety Precautions, Default Configuration Settings of the Sapphire Pump

Update 1: **Continuous Bolus Rate** Default value was changed to 125 ml/h

Update 2: **PCA/PCEA Max Bolus per** feature name was changed to **Limit Period**

- The feature is accessible to High authorization level and above.
- The feature is available only on PCA/PCEA/Epi. Int Options menu.

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

Changes to Chapter 2: Managing Authorization Levels; Section: Overview

Update: Note regarding the pump passwords was added

The following note was added at the end of the section: It is recommended to change the authorization level passwords from the factory defaults, to avoid unauthorized users from accessing the pump. To change a password see page 139 in the Service Manual.

Changes to Chapter 3: Maintenance and Storage; Section: Cleaning and Disinfection: Safety Precautions

Update 1: Additional bullet was added to the list of safety precaution guidelines

Do not clean the pump with bleach (8.25% concentration, mixed at 1 part bleach in 10 parts water), as deterioration may occur.

Changes to Chapter 3: Maintenance and Storage; Section: Cleaning and Disinfecting Procedure

Update: One cleaning agent was added to the table

Cleaning/Disinfecting Solution	Manufacturer
Virox® AHP 5 RTU	Diversey

Changes to Chapter 3: Maintenance and Storage; Section: Cleaning and Disinfecting Procedure

Update: The caution note was replaced

The caution note was replaced with the following caution note:

Before using materials other than the products listed above for cleaning and disinfecting the Sapphire Infusion pump, make sure they are listed in Q Core's official approved list of materials (published at www.qcore.com)

Changes to Chapter 3: Maintenance and Storage; Section: Preventative Maintenance, Alarm Testing

Update: New instructions regarding Sapphire Epidural pumps

To perform the manual testing of the Air in Line alarm and Occlusion alarm in Sapphire Epidural pumps refer to the 'Field Air Detector Test for Sapphire, SapphireH100 and SapphirePlus Infusion Pumps' (P/N 15025-042-0057) and 'Field Occlusion Test for Sapphire SapphireH100 and SapphirePlus Infusion Pumps' (P/N 15020-042-0006).

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

These Testing Protocols can be found on Q Core FTP site (<https://qcore.smartfile.com>). For information regarding the FTP site, refer to the FTP site on page 28 of the Service Manual.

Changes to Chapter 3: Maintenance and Storage; Section: Preventative Maintenance, Built-in Test

Update: Updated instructions regarding failure resolution

The table on page 49 is outdated and should no longer be used. For any failure in the built-in test contact service@qcore.com or the local Hospira service center.

Changes to Chapter 3: Maintenance and Storage; Section: Battery Care Information

Update: Clarification regarding pump operation on battery power

The paragraph preceding the table was replaced with the following:

The Sapphire pump can operate on battery power, enabling operation of the pump during an electrical power failure, during patient transport or during ambulatory care. When working on battery power (disconnected from main power supply) the battery charge level icon, at the upper right corner of the indicators bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly.

Changes to Chapter 4, Performing the Annual Certification Test; section: Certification due date counting

Update: Certification due date counting method for Sapphire was updated

The certification due date counting method for Sapphire was updated. The certification due date counting method in software revision 13.2 is the same as in SapphirePlus software:

The condition for determining the start date when counting the certification due date is the shorter of the two following options:

- 10 working hours
- 2 years from the date of the pump shipment from Q Core Medical's warehouse

When either of the above conditions is met, the next certification date is a dynamic value that will be calculated according to calibration days left from current date (calibration days = certification date + 380 – current date):

- 10 hours condition: Certification date is set to the date the 10 working hours were completed
- 2 years condition: Certification date is set to the original certification date + 2 years

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
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Before the above conditions are met, the calibration days will be calculated as follows:

Certification date + 2 years + 380 days – current date.

The next certification date in the **View System** menu will be calculated according to the calibration days that were left from the current date.

After performing the certification process, the next certification due date is set to the date of the computer that performed the test.

The tolerance is +-7 days.


The certification due date counting method for SapphireH100 has not been changed.

Changes to Chapter 4: Performing the Annual Certification Tests, Getting started

Update: Clarification regarding the treatment needed to be programmed prior to performing the ACT

Program a treatment prior to performing the ACT according to the following table. The described below substitutes step 3 in the section To Perform the Setup Sequence, as it appears on pages 82-84 of the Service Manual.


Note: Steps 1 and 2 in the section To perform the Setup Sequence on page 82 of the Service Manual haven't changed.

Pump Type	Software Revision	With/Without Drug Library	Remove Drug Library prior to ACT	Treatment to Program
Sapphire Multi-Therapy 	Revision 9	Not applicable	Not applicable	a. Select Continuous delivery mode b. Configure treatment: Rate =100ml/h, VTBI =100ml c. Proceed to steps 1-4 described on page 4 below
	Revision 11	With	No	a. Select Continuous delivery mode b. Configure a treatment with Drug Name ="General" c. Configure treatment: Rate =100ml/h, VTBI =100ml d. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select Continuous delivery mode

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Pump Type	Software Revision	With/Without Drug Library	Remove Drug Library prior to ACT	Treatment to Program
				b. Configure treatment: Rate =100ml/h, VTBI =100ml c. Proceed to steps 1-4 described on page 4 below
	Revision 13	With	No	a. Select Continuous delivery mode b. Configure a treatment with Drug Name ="General" c. Configure treatment: Rate =100ml/h, VTBI =100ml d. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select Continuous delivery mode b. Configure treatment: Rate =100ml/h, VTBI =100ml c. Proceed to steps 1-4 described on page 4 below


Pump Type	Software Revision	With/Without Drug Library	Remove Drug Library prior to ACT	Treatment to Program
Sapphire Epidural 	Revision 9	Not applicable	Not applicable	a. Select PCEA delivery mode b. Configure treatment: VTBI =100 ml, Continuous Rate =10 ml/h, Demand bolus =0mL, No loading Dose c. Proceed to steps 1-4 described on page 4 below
		With	Yes	a. Select PCEA delivery mode b. Configure treatment: VTBI =100 ml, Continuous Rate =10 ml/h, Demand bolus =0mL, No loading Dose c. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select PCEA delivery mode

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Pump Type	Software Revision	With/Without Drug Library	Remove Drug Library prior to ACT	Treatment to Program
				b. Configure treatment: VTBI=100 ml, Continuous Rate=10 ml/h, Demand bolus=0mL , No loading Dose c. Proceed to steps 1-4 described on page 4 below
	Revision 13	With	No	a. Select PCEA delivery mode b. Configure a treatment with Drug Name="General" c. Configure treatment: VTBI=100 ml, Continuous Rate=10 ml/h, Demand bolus=0mL , No loading Dose d. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select PCEA delivery mode b. Configure treatment: VTBI=100 ml, Continuous Rate=10 ml/h, Demand bolus=0mL , No loading Dose c. Proceed to steps 1-4 described on page 4 below

Pump Type	Software Revision	With/Without Drug Library	Remove Drug Library prior to ACT	Treatment to Program
SapphireH100 	All	With	No	a. Select Continuous delivery mode b. Configure a treatment with Drug Name="General" c. Configure treatment: Rate=100ml/h, VTBI=100ml d. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select Continuous delivery mode b. Configure treatment:

				Rate=100ml/h, VTBI=100ml c. Proceed to steps 1-4 described on page 4 below
SapphirePlus 	All	With	No	a. Select Continuous delivery mode b. Configure a treatment with Drug Name="General" c. Configure treatment: Rate=100ml/h, VTBI=100ml d. Proceed to steps 1-4 described on page 4 below
		Without	Not applicable	a. Select Continuous delivery mode b. Configure treatment: Rate=100ml/h, VTBI=100ml c. Proceed to steps 1-4 described on page 4 below

1. In the **Confirm** screen confirm treatment by pressing **OK**.
2. In the **Start** screen exit the treatment by pressing **Exit**.
3. Verify that the option **Repeat Last Infusion** is available (don't select it). If not, repeat steps 1-3.
4. Proceed to the section **To Perform the Preliminary Inspections** on page 85 of the Service Manual.

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Changes to Chapter 5: Downloading Event Log

Update: Chapter removed

The chapter **Downloading Event Log** has been removed.

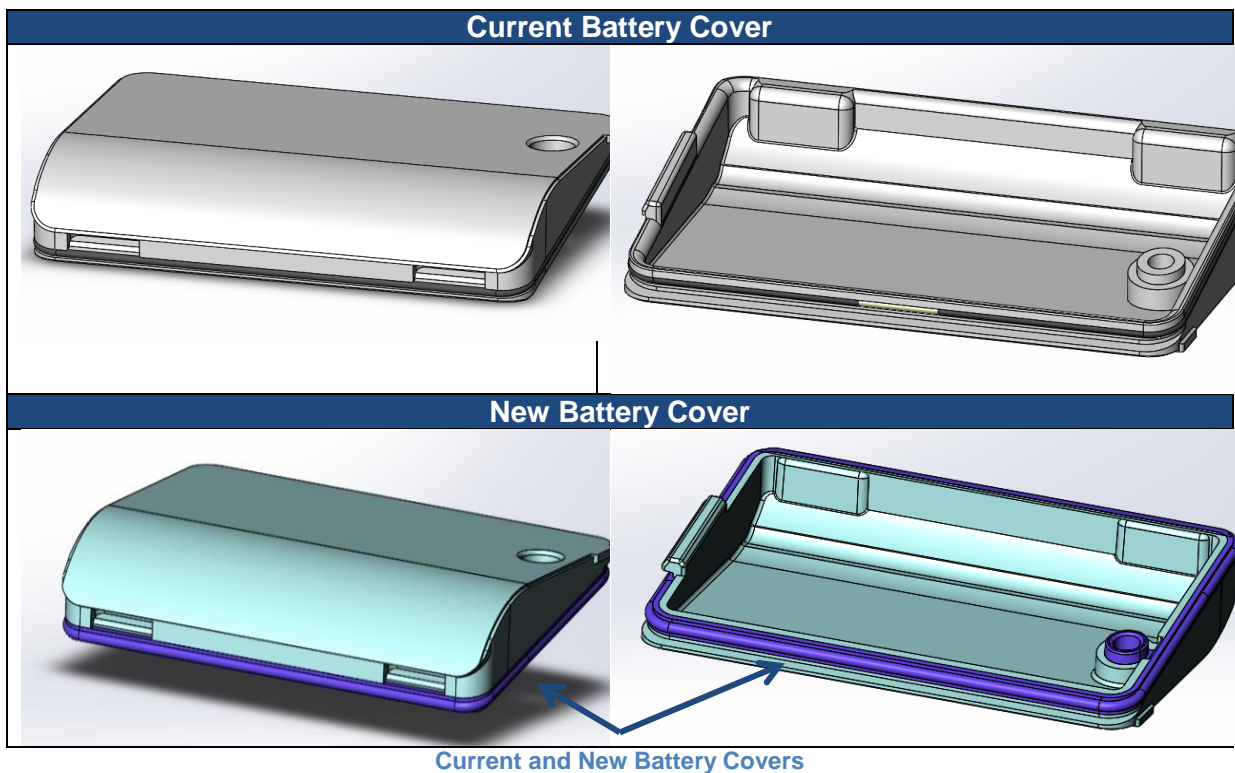
The Events Viewer software and its DFU (Directions for Use, 16008-003-0001) can be obtained from Q Core Medical FTP site (<https://qcore.smartfile.com>). The DFU includes the list of all pump events.

Changes to Chapter 6: Replacing the Battery

Update: New battery cover

The new battery cover includes an over-mold seal instead of the previous O-ring seal. For pumps with the O-ring seal on the battery cover, verify that the O-ring cannot be seen after closing the battery cover.

For pumps with the over-mold seal on the battery cover, verify that the over-mold is not pinched and not seen after closing the battery cover.



Changes to Chapter 7: Sapphire & SapphireH100; Section: Configuring Basic Pump Settings, Managing Alarm Settings

Update 1: The Occlusion pressure option was updated in SapphireH100, software 13.22.3

The **Occlusion pressure** option name was changed to **Occlusion Alarm**. The **Occlusion Alarm** option is described in the table below:

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Occlusion Alarm	The minimum downstream pressure that triggers an Occlusion alarm. Acceptable ranges are 1.5 to 17.4 PSI, 0.1 to 1.2 BAR or 75 to 900 mmHg. An alarm sounds when the downstream pressure reaches the set value \pm the sensor sensitivity level. During infusion, the current downstream pressure is displayed on the Pressure display screen (for more information refer to the SapphireH100 User Manual) and on the screen saver.	Select Occlusion Alarm . Then, using the keypad, enter the desired value and press OK.

Update 2: Infusion near end alarm description changed

In the option **Infusion near end**, the note in the Descriptions/Notes column was removed.

Changes to Chapter 7: Sapphire & SapphireH100; Section: Configuring Basic Pump Settings, Configuring General Settings

Note: All updates in chapter 7 are relevant for Sapphire only (and not for SapphireH100) unless stated otherwise

Update 1: A new menu under Pump Configuration named Audio settings was added

The Audio settings menu includes the following settings:

Setting	Description	Default Value
Keys Volume	Sets the speaker volume for the auditory signal generated when the user selects functions and presses keys on the pump.	High
Alarm Volume	Sets the speaker volume for the auditory alarm signal. Options are Maximum or Minimum . When the option is set to Minimum , messages are provided with a visual signal only. Alarm	Maximum

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	<p>levels 1, 2 and 3, and the “Infusion Complete” message are provided with a visual signal and the lowest auditory signal permitted according to IEC 60601-1-8.</p> <p>Maximum alarm volume is 70 dB.</p> <p>Minimum alarm volume is 56 dB.</p> <p>Note: Auditory alarm signal sound levels which are less than ambient levels can impede operator recognition of alarm conditions.</p>	
Bolus Handle	<p>Sets the Bolus auditory signal generated when the bolus handle is pressed.</p> <p>When the option is set to Always On, an auditory signal is generated each time the bolus handle is pressed. When set to When Bolusing, an auditory signal is generated upon pressing of the bolus handle only when bolus is available.</p>	On

Update 2: The General settings menu was updated

The General settings menu includes the following settings.

To save changes press **Next** and then **OK**.

Setting	Description	To Modify Parameter (from the General settings screen)
Current CCA	Used to select the CCA to which the pump should be set. Appears only when a Drug Library is loaded.	Select Current CCA . Choose the appropriate CCA; then, from the Attention screen press OK .
Start Up Config.	Set the configuration of the Start Up screen. Includes Repeat Last Infusion and PreProgram options. When the Repeat Last Infusion option is enabled, the Repeat Last Infusion frame appears on the Start Up screen.	See the User Manual
Authorization level	Sets the authorization lock level of the pump.	Select Authorization level . Then, enter a password and select Low , Medium , High or Tech .
Allow delayed start	Enables/disables programming of infusions that begin after a predefined period of time (or after standby). When the	Select the Allow delayed start row, to toggle the option between

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Setting	Description	To Modify Parameter (from the General settings screen)
	option is enabled, the Set Delay frame appears on the Start screen.	On and Off .
Set Prime Volume	The amount of fluid used to prime the administration set when automatic priming is performed. The acceptable range is 2 to 25 mL. If a value outside the permitted range is entered during programming, the OK function key is disabled.	Select Set prime volume . Then, using the keypad, enter the desired value and press OK .
Backlight	Sets the degree of screen dimming while the pump is running. The Off and Partial options of this feature save power and promote longer battery life.	Select Backlight . Then, select On , Off or Partial .
Prime Reminder	Enables a reminder for the user to prime the administration set before starting an infusion.	Select the Prime Reminder row, to toggle the option between On and Off .
Advanced Bolus	Allows users to program a bolus by entering rate, amount and time. When this option is disabled, the bolus is programmed by amount only, and the rate is the default bolus rate. The option is available only when Allow Bolus is enabled (under Technician options). Applicable only for the Continuous delivery mode.	Select the Advanced Bolus row, to toggle the option between On and Off .
Bolus Reminder	Enables a reminder for the user to connect the bolus handle before starting a PCA, PCEA or PIEB infusion that includes patient boluses. The reminder: <ul style="list-style-type: none"> • Instructs to connect the bolus handle directly to the pump. • Checks functionality – bolus press is recognized by the pump. 	Select the Bolus Reminder row, to toggle the option between On and Off .
Auto. P. Lockout	Enables/disables Patient Lockout , a safety feature that requires password entry to make any parameter changes. When the option is enabled, Patient Lockout is activated automatically when an infusion begins.	Select the Auto P. Lockout row, to toggle the option between On and Off .
Screen Saver	Enables/disables a far-view display of the main infusion parameters during a running infusion. These include drug information,	Select the Screen Saver row, to toggle the option between On and Off .

Setting	Description	To Modify Parameter (from the General settings screen)
	<p>delivery mode (color indication), infusion rate and the current phase (dose, continuous rate, etc.). In SapphireH100, software 13.22.3, the pressure bar will also be displayed.</p> <p>The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched.</p> <p>The screen saver will not appear in the following cases: Delayed start, end of infusion KVO, or during a Bolus delivery.</p> <p>The screen saver will disappear in the following cases:</p> <ul style="list-style-type: none"> ○ Alarm - screen will revert to the alarm screen ○ Touching the screen - screen will revert to the Running screen ○ Infusion is paused - screen will revert to the Paused screen. 	

Changes to Chapter 7: Sapphire & SapphireH100; Section: Configuring Basic Pump Settings, Defining Regional Parameters

Update: The US format option was moved to the Regional menu

The US format option was moved from the menu: **Technician options->Pump settings->General** to the menu: **Pump configuration->Regional**.

Select the **US format** row to toggle the option between **On** and **Off**.

Changes to Chapter 7: Sapphire & SapphireH100; Section: Using Technician Options, Managing Pump Settings, Setting Hard Limits

Update 1: The hard limits table for TPN and Intermittent delivery modes was updated

Delivery Mode	VTBI	Max Dose Time	Int. Dose
TPN	V		
Intermittent	V	V	V

Update 2: The hard limits table for PCA, PCEA and Epidural Intermittent delivery modes was updated

Delivery Mode	VTBI	Int. Dose	Continuous Rate	Demand Bolus*	Loading Dose	Bolus Rate	Min Bolus Lockout	Max Bolus Lockout
PCA	V		V	V	V	V	V	V
PCEA	V		V	V	V		V	V
Epi. Int	V	V		V**			V**	V**

* Changing the hard limits of the **Demand Bolus** parameter also applies to the **Clinician Bolus** parameter.

** The hard limits of this option can be only changed when PIEB is set to **On** (in the **Epi. Int.** menu).

Changes to Chapter 7: Sapphire & SapphireH100; Section: Using Technician Options, Managing Pump Settings, Resetting the System

Update: The Reset system menu was updated

The Reset System option is used to:

1. Revert all pump parameters and features to the factory defaults settings
2. Define new security passwords
3. Remove the Drug Library
4. Remove the PrePrograms

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Factory defaults

- Select **Factory defaults**. The Attention screen appears
- To confirm the reset press **OK**

Changes are saved in the system and the Start Up screen appears.

Passwords

- Select **Passwords**
- Select authorization level or **PreProgram** password to change
- In **PreProgram** enter a 4-digit password in the specified range [1000 - 9999]. In an authorization level enter a 4-digit password in the specified range [1000 - 7000]

Note: Passwords for each security level must be unique and in the specified range. The **OK** button will be disabled when entering the same password for more than one security level.

The **PreProgram** password can be identical to an authorization level password, yet there is no connection between the options the authorization level enables and the **PreProgram** option.

Press **OK** to save the changes.

Remove Drug Library

The Drug Library can only be removed by users with Technician authorization level. This option will be hidden if there is no Drug Library on the pump. When the user removes the Drug Library all parameters are set to factory defaults.

- Select **Remove Drug Library**
- Press **OK** to confirm. The Start Up screen will appear

Remove PrePrograms

Enables the removal of all preset programs configured on the pump (in all delivery modes).

- Select **Remove PrePrograms**
- Press **OK** to confirm. The Start Up screen will appear

Changes to Chapter 7: Sapphire & SapphireH100; Section: Using Technician Options, Managing Pump Settings, Configuring General Settings

Update 1: The menu General under Pump settings (under Tech. options) was updated

Setting	Description	Default Value
Delivery Mode	Determines the available delivery modes. Each mode can be turned off separately.	On
New patient	Allows users to associate an infusion with patient identification parameters, and reset the Accumulated VI (accumulated volume infused).	Off
Occ. Auto-restart	Enables the pump to automatically restart an infusion, up to 5 times an hour, if a downstream occlusion was detected and cleared within 40 seconds.	On
Calculate Concentration	Determines if the user enters final concentration or Drug Amount and Diluent Volume .	Off
mL/h only	Enables the user to use units other than mL/h. If this option is disabled, programming will automatically default to mL/h. This feature is available in the absence of a Drug Library on the pump.	Off
Med. Titration	Allows users with medium authorization level to change rate during a running infusion.	Off

The following settings appear only when the pump is in Continuous delivery mode.

To save changes press **Next** and then **OK**.

Setting	Description	Default Value
Set Secondary (Piggyback)	Allows users to program a Secondary infusion.	Off
Allow Bolus	Allows users to program a bolus during a Continuous infusion. When this feature is enabled, the Bolus button appears in the toolbar during the running infusion.	Off
Bolus Rate	Specifies the rate of delivery of a fast dose, for rapid volume infusion.	125 mL/h
Sec. Bolus Rate	Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion.	125 mL/h

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Update 2: The table on page 142 was updated

The following settings appear **only in PCA, PCEA and Epi. int Options menu** (relevant for Sapphire only).

Setting	Description	Default Value
Limit Period	Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses will be limited by either maximum number, or by maximum volume). Options are 1 hour or 4 hours.	1 h(s)

Changes to Chapter 7: Sapphire & SapphireH100; Section: Alarms and Troubleshooting, Level 2 Alarms

Update: The alarm titled **Battery Fault** regarding battery tampered was canceled

Changes to Chapter 7: Sapphire & SapphireH100; Section: Alarms and Troubleshooting, Level 3 Alarms

Update: Four alarms added to the Level 3 Alarms table, in Sapphire and SapphireH100

Alarm Title	Displayed Text
Air in Line	Please prime administration set. If problem reoccurs, remove and reinsert the cassette
Air in Line	Possible excessive environmental light. Please reduce exposure and check if priming is required
Pump Stopped	Please quit and then restart the infusion
Potential Air in Line	Press OK to test for air

Changes to Chapter 7: Sapphire & SapphireH100; Section: Alarms and Troubleshooting, Messages

Update: New message added to the messages table

Message Title	Displayed Text
Message	Key stuck. Please release the key

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

Changes to Chapter 7: Sapphire & SapphireH100; Section: Alarms and Troubleshooting, Guidance in Problem Solving

Update: Clarification regarding troubleshooting in Sapphire and SapphireH100

For troubleshooting in Sapphire and SapphireH100 refer to the **Troubleshooting** section on page 202 of the Service Manual.

Changes to Chapter 7: Sapphire & SapphireH100; Section: Alarms and Troubleshooting, Guidance in Problem Solving, Alarms Description List

Update: New type of Air in Line alarm

Alarm Title	Description	Solution
Air in Line	Excessive environmental light, in addition to the regular Air in Line conditions, was detected	Normal course of operation. Not a pump malfunction

Changes to Chapter 7: Sapphire & SapphireH100; Section: Upgrading Software Version

Update 1: Updated software upgrade procedure

The following procedure describes how to update the Sapphire pump software. This procedure replaces the **Upgrade Procedure** described in pages 159-161 of the Service Manual.

Use the most updated version of the Pump Loader. The most updated version of the Pump Loader can be found on Q Core FTP site (<https://qcore.smartfile.com>).

The Pump Loader is compatible with all approved pump software revisions.

SapphirePlus pump software can be updated using the Pump Loader software or using the Wi-Fi connection (see the Service Manual, chapter 8, SapphirePlus).

Up to 8 Pump Loader instances can be used simultaneously on one computer.**Note:** Informing Q Core on pump software update:

- In case the Pump Loader (version 13.21.0 and above) is used for the software update it is not required to fill in and submit the Customer Software Upgrade Form (page 213 on the Service Manual).

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- For SapphirePlus pumps, if the Wi-Fi is used (MedNet) for the software update, it is required to fill in and submit the Pump Software Update Using MedNet form (15038-049-0001) as provided on Q Core FTP site. This form should be submitted electronically (soft copy) to service@qcore.com.

Before starting the procedure:

- Connect the pump to the power supply. Otherwise, verify the pump's battery is fully charged.
- If using the USB-to-RS232 adaptor, verify that the adaptor driver is installed on the computer prior to connecting the pump to the computer.
- Verify that the software to be updated on the pump is compatible with the pump:
 - **All modes** software: installed on Sapphire Multi-Therapy pumps
 - **Epidural only** software: installed on Sapphire Epidural pumps
 - **SapphireH100** software: installed on SapphireH100 pumps
 - **SapphirePlus** software: installed on SapphirePlus pumps

Note: The Pump Loader software requires communication with Q Core server. In case of communication problems refer to the troubleshooting section below.

Hardware requirements:

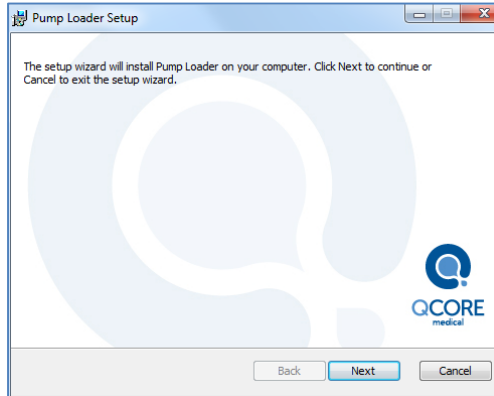
- PC: Pentium 4, 1500MHz CPU, 512 RAM (or higher)
- Screen resolution 1280x1024 (minimum)
- Communication cable for the Sapphire pump (P/N 05020-110-0213)
- RS232 connectivity in either of the following forms:
 - RS232 port in the computer
 - USB to RS232 adaptor + driver (P/N 15077-000-0001)
- Internet connection (open port TCP 5100 to host name:
applicationsserver.qcore.com for communicating with Q Core server)

Software requirements:

- OS: Win XP 32 / 64 bit, Win 7 32/64 bit, Win 8.1 32/64 bit, Win 10 64 bit
- .Net framework 4.0

Installing the Pump Loader software:

1. Download the setup file **Pump Loader Setup** (.msi file) from Q Core Medical FTP site to a directory of your choice.
2. Double-click the **Pump Loader Setup** file to start the installation process and click **Next**.
3. Review the license agreement details and check the relevant checkbox to accept.
4. It is possible to create shortcuts to the Pump Loader software; Check/uncheck the relevant checkbox, as desired.
5. Click **Install**.
6. After the installation has completed, click **Finish**.



Pump Loader Setup

Updating the pump software:

Note: prior to starting the software update process verify that:

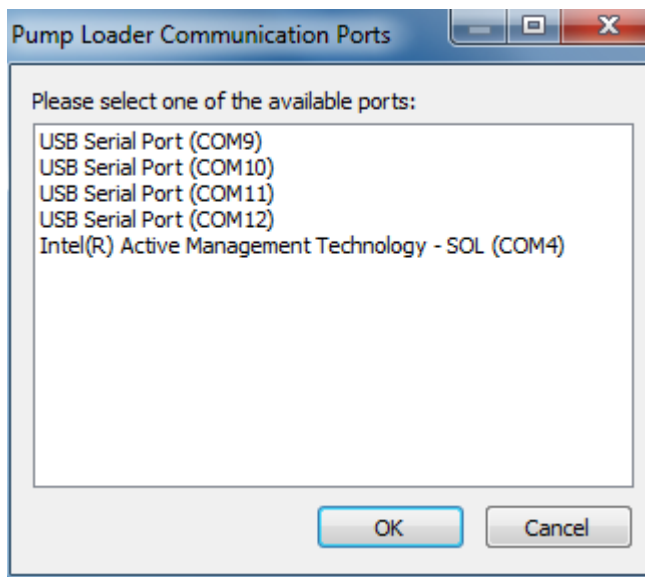
- The computer is connected to the internet
- The internet connection has an open port TCP 5100 to host name: **applicationsserver.qcore.com** for communicating with Q Core server
- The sleep mode on the computer is disabled; failing to do so may result in upgrade failures

Software Update Process:

1. Turn the pump on. Connect the pump to the computer using the communication cable. You may also use the USB-to-RS232 adaptor.
2. Open the Pump Loader software by double-clicking the **Pump Loader** icon.
3. The window **Pump Loader Communication Ports** opens. Select the suitable COM port and then click **OK**.

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Pump Loader Communication Ports window

4. The main screen of the Pump Loader appears. After a few seconds the **Status** field should indicate **Pump connected**. If the status field indicates **No device connected** verify that the pump is connected properly to the computer via the correct COM port.
In case of communication problems refer to the troubleshooting section below.

The main screen of the Pump Loader includes the following fields (see figure below):

Field Name	Function
File menu	The Exit option is used to exit the Pump Loader
Help menu	Includes the options Show Instructions (Hide Instructions after Show is selected) and About . The Show Instructions option shortly explains how to upload software on the pump. The About option displays the Pump Loader version information.
Status	Indicates if the pump is connected to the computer and the status of the upload process
Pump SN	Displays the serial number of the pump
Pump SW Version	Displays the current software version of the pump
Other - browse... dropdown list	A list of the possible software to upload on the pump. This function will be available in the future
Load button	Allows the selection of the software to upload to the pump
Package File	Displays the software that is being uploaded to the pump
Two progress bars	Indicating the progress of the upload. The bottom



Field Name	Function
	progress bar indicates the status of the overall progress
Progress	A table displaying the actions performed by the Pump Loader



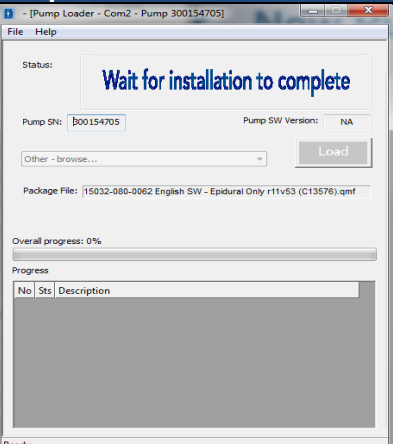
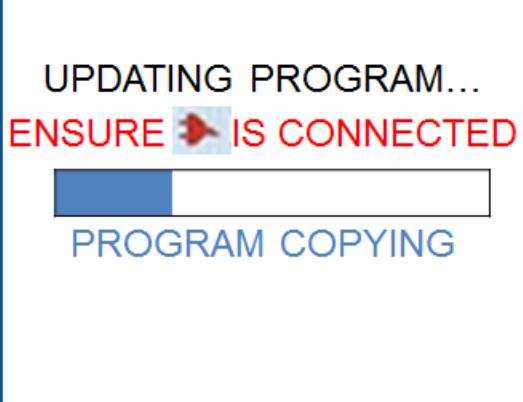
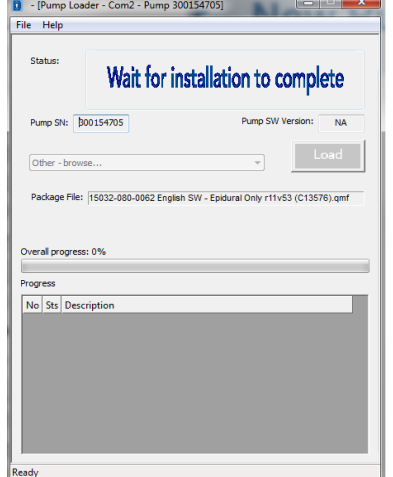

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Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

- Click **Load**. Select the software to upload to the pump by double-clicking on the software file. The upload will start automatically.

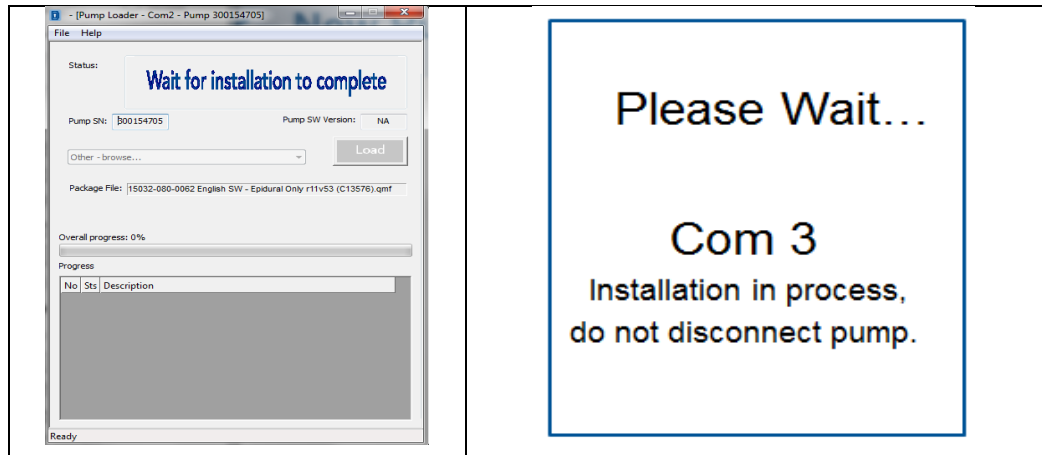
Note: Do not turn the pump off or disconnect it from the computer while the update is in progress.

During the update process, after the boot mode, the following screens appear on the computer and on the pump:

Computer Screen	Pump Screen
	
	

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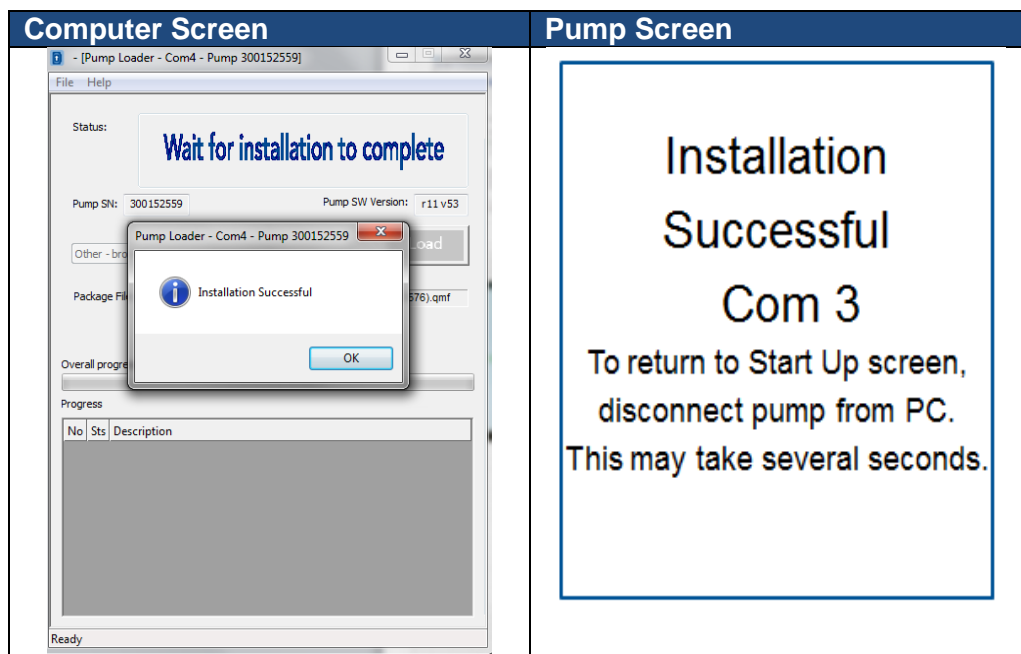
Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1



Software update in process

6. The pump software update is completed when a message stating the update was completed successfully is displayed on the computer and on the pump. See picture below.

Note: Do not disconnect the pump from the computer before the messages of successful update appear both on the computer and on the pump. Pay attention to the relevant COM port.



Software update completed

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Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

After the software update has completed, press OK on the computer, close the Pump Loader and disconnect the pump from the computer. Wait until the “Installation Successful” screen has disappeared and the pump has returned to the Start Up screen. Restart the pump.

7. If the pump software language is not as required, refer to the **Defining Regional Parameters** section on page 130 of the Service Manual.
8. Verify that the desired software was uploaded on the pump. On the pump, go to: **Options-> View-> View system**. Click **Next** until the **Software version** field is displayed. Verify that the software version displayed is as expected.

Note: In any case that the software was not updated successfully it is required to close the Pump Loader, restart it and repeat the software update process.

Troubleshooting

16 new troubleshooting cases were added to the troubleshooting table.

One troubleshooting case was updated.

New troubleshooting cases:

Problem	Solution
Installation failed message was prompted on the pump and/or the computer	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the computer. Wait for the Start Up screen to appear ○ Restart the pump ○ Repeat the software update process
Prime button on Start Up screen is disabled after software upload	<ul style="list-style-type: none"> ○ Move to another screen or restart the pump. The Prime button will be enabled.
After upgrading from revision 11 to revision 13.2, the Dose calculation option does not appear in the Dosing method window, although it was available in revision 11 before the software upgrade	<ul style="list-style-type: none"> ○ Go to the menu: Options->Technician options->Pump settings->General. Press Next. ○ Verify that the mL/h only setting is set to Off.
During the Pump Loader installation the following message is prompted on the computer: “This application requires .NET Framework 4.0 full, please install the .NET Framework and then run the installer	<ul style="list-style-type: none"> ○ Click OK to cancel the installation ○ On the computer: Go to Start->All Programs >Windows Update ○ Select Optional Updates and then select .NET Framework 4.0.

Problem	Solution
again.”	<ul style="list-style-type: none"> ○ Follow the online instructions ○ Double-click the Pump Loader Setup file to start the installation
During the Pump Loader installation the following message is prompted on the computer: “This application is supported on Windows XP, Windows 7 and higher.”	<ul style="list-style-type: none"> ○ Use a computer with the appropriate operating system
The following message is prompted on the computer after the Pump Loader main screen appears: "Automatic connection of the Pump Loader Software to the Q Core server has failed. Contact your system administrator to verify internet connection and port 5100 firewall configurations, and press Retry below. For further information, refer to the Troubleshooting section In the service manual. Press Cancel to exit Pump Loader."	<ul style="list-style-type: none"> ○ Verify the computer is connected to the internet ○ Verify that the internet connection has an open port TCP 5100 to host name: applicationsserver.qcore.com for communicating with Q Core server ○ If the error message keeps appearing contact service@qcore.com or the local Hospira service center.
The following message is prompted on the computer after selecting Yes to exit the Pump Loader: "Process logs saved locally, and will be automatically uploaded to the Q Core Servers during the next connection with Pump Loader. No further action is required, Press OK to exit Pump Loader"	<ul style="list-style-type: none"> ○ The message was prompted due to a loss of communication with Q Core server. Process logs will be uploaded to Q Core server during the next use of the Pump Loader and establishing communication with Q Core server ○ It is recommended to reconnect to the internet, open the Pump Loader, choose a COM port and close the Pump Loader after one minute.
The following error message was prompted on the pump: “Version error Code: 7 Please contact an authorized Technician”	<ul style="list-style-type: none"> ○ Repeat the software update process ○ If the error message keeps appearing contact service@qcore.com or the local Hospira service center
The following error message was prompted on the computer:” The software version you are trying to install is incompatible with your device hardware. Please contact your local distributor. For further information, refer to the service manual"	<ul style="list-style-type: none"> ○ Repeat the software update process ○ Contact service@qcore.com or the local Hospira service center
Installation failed message appears on the pump screen before the software update process started	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the computer. Wait for the Start Up screen to appear ○ Restart the pump ○ Repeat the software update process

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Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
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Problem	Solution
The “Please Wait” screen is displayed on the pump while a failure message is displayed on the computer	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the computer. Wait for the Start Up screen to appear ○ Restart the pump ○ Repeat the software update process
“Software execution failure! Please re-install software” message appears on the pump screen	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the computer. Wait for the Start Up screen to appear ○ Restart the pump ○ Repeat the software update process
After the software update process has completed the pump turns on with a black screen	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Turn the pump off ○ Disconnect the pump from the communication cable and the power supply ○ Disconnect the battery from the pump ○ Wait a few seconds and reconnect the battery ○ Connect the pump to the communication cable and to the power supply ○ Repeat the update process. Even if the status field indicates No device connected, click Load to select the software to upload to the pump. <p>Note: If the following message is prompted: “Application did not recognize any attached device. If you are sure that the device is attached, please select it manually”, click Pump.</p>
No communication between the pump and the computer	<ul style="list-style-type: none"> ○ Verify the communication cable is properly connected ○ If using the USB-to-RS232 adaptor, verify that the adaptor driver is installed on the computer and that it is properly connected ○ If the problem persists contact service@qcore.com or the local Hospira service center
The computer entered sleep mode and the software update failed	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the computer. Wait for the Start Up screen to appear

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Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Problem	Solution
	<ul style="list-style-type: none"> ○ Restart the pump ○ Verify the sleep mode on the computer is disabled ○ Repeat the software update process
<p>This case only relates to pumps that were used less than 10 hours.</p> <p>After updating the pump software from revision 11 or lower to revision 13, the Next certification due date, as it appeared under the View system menu, has changed.</p>	<ul style="list-style-type: none"> ○ Normal course of operation. No further actions required. The Next certification due date, under the View system menu, will be updated after 10 hours of pump operation

Updated troubleshooting case:

Problem	Solution
<p>The text in the screen header appears in red</p>	<ul style="list-style-type: none"> ○ Close the Pump Loader ○ Disconnect the pump from the communication cable and power supply ○ Wait 15 minutes ○ Repeat the update process. Even if the status field indicates No device connected, click Load to select the software to upload to the pump. <p>Note: If the following message is prompted: “Application did not recognize any attached device. If you are sure that the device is attached, please select it manually”, click Pump.</p>

Update 2: Instructions for upgrading the Sapphire pump from software revision 11 to software revision 13.2

After verifying the software was uploaded successfully, change the mL/h only setting: if it is set to **On** change it to **Off**; If it is set to **Off** change it to **On**:

- Enter the menu: Options->Technician options->Pump settings->General. Press **Next**.
- Toggle the mL/h only setting as described above.

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3, SapphirePlus 13.11.1

Changes to Chapter 8: SapphirePlus; Section: Configuring Basic Pump Settings, Managing Alarm Settings

Update: Infusion near end alarm description changed

In the option **Infusion near end**, the note in the Descriptions/Notes column was removed.

Changes to Chapter 8: SapphirePlus; Section: Using Technician Options, Managing Pump Settings, Configuring General Settings

Update 1: There is no default value for the **Wi-Fi** option

Update 2: Bolus rate and Secondary Bolus Rate default values updated (relevant only to continuous delivery mode)

The Bolus rate and Secondary Bolus rate default values were updated to 125mL/h.

Changes to Chapter 8: SapphirePlus; Section: Alarms and Troubleshooting, Level 2 Alarms

Update: The alarm titled **Battery Fault** regarding battery tampered was canceled

Changes to Chapter 8: SapphirePlus; Section: Alarms and Troubleshooting, Level 3 Alarms

Update: Four alarms added to the Level 3 Alarms table

Alarm Title	Displayed Text
Air in Line	Please prime administration set. If problem reoccurs, remove and reinsert the cassette
Air in Line	Possible excessive environmental light. Please reduce exposure and check if priming is required
Potential Air in Line	Press OK to test for air
Pump Stopped	Please quit and then restart the infusion

Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Changes to Chapter 8: SapphirePlus; Section: Alarms and Troubleshooting, Messages

Update 1: Three messages added to the messages table

Screen Header	Displayed Text
Message	Key stuck. Please release the key
Message	WiFi disconnected. To reconnect WiFi, connect pump to power supply
Message	WiFi disconnected. Please contact authorized technician. Press OK to continue without WiFi

Update 2: Message removed from the messages table

The message “WiFi communication problem. Press OK to continue without WiFi connection.” was removed from the messages table.

Changes to Chapter 8: SapphirePlus; Section: Alarms and Troubleshooting, Guidance in Problem Solving, Alarms Description List

Update: New type of Air in Line alarm

Alarm Title	Description	Solution
Air in Line	Excessive environmental light, in addition to the regular Air in Line conditions, was detected	Normal course of operation. Not a pump malfunction

Changes to Chapter 8: SapphirePlus; Section: Alarms and Troubleshooting, Troubleshooting, Non-technical Troubleshooting

Update: One new troubleshooting case added

Description of Problem	Solution
Occlusion alarm is triggered immediately after the infusion or bolus starts, or rate is increased	In cases where the backpressure caused by the catheter used for the treatment, at the programmed rate, is too high- reduce the backpressure by either replacing the catheter or by decreasing the infusion rate



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Updated to Sapphire 13.21.1 and 13.22.1, SapphireH100 13.22.3,
SapphirePlus 13.11.1

Changes to Chapter 8: SapphirePlus; Section: Upgrading Software Version

Update 1: To view the current software version select: **Options->View->View system.**
Press **Next**

Update 2: Informing Q Core on pump software updates using the Mednet

For SapphirePlus pumps, if the Wi-Fi is used (MedNet) for the software update, it is required to fill in and submit the Pump Software Update Using MedNet form (15038-049-0001) as provided on Q Core FTP site. This form should be submitted electronically (soft copy) to service@qcore.com.